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Attorney's Docket No.: 11544-003001 / 0641-5101US

### REMARKS

This document is filed in reply to the Office Action dated October 6, 2004 ("Office Action"). Applicants have amended claims 1, 24, 25, 27, 35, 36 and 37 to promote clarity. Applicants have also withdrawn claims 30-33. No new matter has been introduced.

Claims 1, 3-5, 7-9, and 11-37 are pending. Among them, claims 1 and 11 have been examined. Contrary to the Examiner's statement in the Office Action, claims 3 and 23-29 and 34-37 have never been withdrawn. Reconsideration of claims 1 and 11, as well as claims 3, 23-29, and 34-37, is respectfully requested in view of the following remarks.

#### Rejection under 35 U.S.C. § 112, second paragraph

The Examiner rejected claims 1 and 11 for indefiniteness. See the Office Action, page 2, lines 10-18. Applicants have amended claim 1, from which claim 11 depends. It is respectfully submitted that this rejection has been overcome.

#### Rejection under 35 U.S.C. §§ 102(b) and 103(a)

The Examiner rejected claims 1 and 11 as being anticipated or rendered obvious by Yoshikawa et al. (Chem. Pharm. Bull. 1998 vol. 46, no. 4, pp 647-654, "Yoshikawa"). See the Office Action, page 3, lines 2-4. Applicants respectfully traverse and discuss claim 1 first.

Claim 1, as amended, covers a composition containing an American ginseng extract obtained by extraction, centrifugation, and filtration with an ultrafiltration membrane having a molecular weight cut-off of at least 1000 to remove compounds having molecular weights of below 1000 dalton.

In the last response, Applicants pointed out that Yoshikawa *et al.* teaches a methanolic extract and several fractions from American ginseng. This methanolic extract was prepared without removing compounds having molecular weights of below 1000 dalton. Yoshikawa also teaches several fractions that were prepared from American ginseng by silica gel column chromatography or HPLC. It is well known in the art that both techniques separate compounds from each other by partitioning between the

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stationary packing material (silica) and the mobile eluent. Compounds with different polarity partition to different extents. As a result, they move through a silica gel column chromatography or HPLC column at different rates and give different eluents or fractions. In other words, Yoshikawa teaches preparing fractions from American ginseng based on polarity differences of compounds. It does not teach or suggest doing so based on molecular weight differences of the compounds, let alone removing compounds having molecular weights of below 1000 dalton as required in claim 1. As the fractions taught in Yoshikawa contain compounds having molecular weights of below 1000 dalton, they differ from that recited in claim 1.

The Examiner countered that

Yoshikawa teaches isolating compounds with a molecular weight greater than 1,000. Since the compounds are isolated, there are no components except that are over the molecular weight of 1,000. Thus, the compounds isolated by Yoshikawa are the same as the claimed compounds. Since applicant's claims are directed to product-by-process claims, the claims are properly rejected under the prior art if the prior art structure reasonably appears to be the same as the claimed structure. In this case, [the] Yoshikawa [structure] does appear to be the same [as the claimed] structure because the reference teaches isolated American ginseng compounds that are above 1,000 daltons. (See the Office Action, page 3, paragraph 2)

In short, according to the Examiner, the American ginseng extract recited in claim 1 only contains compounds identical to the "compounds isolated by Yoshikawa."

As mentioned above, the American ginseng extract recited in claim 1 is obtained by, among others, removing compounds having molecular weight of less than 1000. It therefore only contains compounds that have molecular weights of at least 1000. Indeed, the extract contains compounds having molecular weights of at least 3000, 10000, or 100000, as support by Example 2 in the Specification,<sup>1</sup> as well as JP 04316507A1 and JP 61109732A1.<sup>2</sup>

<sup>1</sup> In this example, American ginseng substances with molecular weights of greater than 3,000 were obtained by extraction, centrifugation, and filtration with an ultrafiltration membrane with molecular cut-off at least 3,000. See page 7, lines 17-19. The process recited in amended claim 1 affords a American ginseng substances in the same manner, except that it uses an ultrafiltration membrane with a molecular cut-off of at least 1,000, instead of 3,000. It follows that the American ginseng extract recited in claim 1 contains

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Yoshikawa discloses 5 compounds isolated from American ginseng, i.e., quinquenoside I ( $C_{52}H_{80}O_{19}$ ), quinquenoside II ( $C_{62}H_{104}O_{24}$ ), quinquenoside III ( $C_{50}H_{84}O_{19}$ ), quinquenoside IV ( $C_{54}H_{90}O_{24}$ ), and quinquenoside V ( $C_{60}H_{102}O_{28}$ ). See chart 1. Applicants note that the molecule weights of these compounds are 1014, 1232, 988, 1122, and 1270, respectively. Yoshikawa also mentions 21 other compounds from American ginseng (see chart 3). The largest of these 21 compounds, malonyl-ginsenoside-Rb<sub>1</sub>, has a molecule weight of 1160. Put differently, Yoshikawa only teaches isolating from American ginseng compounds having molecular weights of around 1000. It does not teach or suggest isolating from American ginseng any compounds having molecular weights of at least 3000, as contained in the American ginseng extract recited in claim 1. Thus, the American ginseng extract recited in claim 1 contains compounds that differ from those isolated by Yoshikawa.

For the reasons set forth above, Applicants submit claim 1 is not anticipated or rendered obvious by Yoshikawa. Neither are claims 3, 11, 23-29 and 34-47, all of which depend from claim 1.

### CONCLUSION

For the above remarks, Applicants submit that the grounds for rejection asserted by the Examiner have been overcome, and the claims, as pending, define subject matter that is definite, novel, and non-obvious. On this basis, it is submitted that allowance of this application is proper, and early favorable action is solicited.

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substances with molecular weights of greater than 1000, including those with molecular weights of greater than 3000.

<sup>2</sup> JP 04316507A1 and JP 61109732A1, both previously cited by the Examiner, respectively teach that American ginseng contains compounds that have molecular weights of at least 10000 and 100000.

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Enclosed is a Petition for One Month Extension of Time. Please apply the required fee of \$60, and any other charges, to deposit account 06-1050, referencing attorney docket 11544-003001.

Respectfully submitted,

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